



April 25, 2019

VIA HAND DELIVERY AND ELECTRONIC MAIL

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Washington, DC 20510

Hon. Patty Murray
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Hon. Ron Wyden
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Hon. Chris Van Hollen
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Dear Senators:

I write in response to your April 8, 2019 letter. JUUL Labs, Inc. (“JLI”) welcomes the opportunity to discuss its business and the steps it is taking to combat the problem of underage use of its products.

JLI was founded with one objective: to eliminate the use of combustible cigarettes by developing products that help smokers make the switch to a less harmful alternative. We are also very focused on preventing youth use of our products, as reflected in the measures we have taken described more fully below.

The facts for adult smokers and their loved ones speak for themselves. Cigarette smoking remains the leading cause of preventable disease and death in the United States, responsible for more than 480,000 deaths each year.¹ Cigarette smoke contains over 7,000 chemicals, at least 250 of which are known to be harmful and at least 69 of which can cause cancer.² And many of these

¹ *Smoking & Tobacco Use: Fast Facts*, Center for Disease Control and Prevention, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm.

² *Harms of Cigarette Smoking and Health Benefits of Quitting*, National Cancer Institute, <https://www.cancer.gov/about-cancer/causes-prevention/risk/tobacco/cessation-fact-sheet>.

chemicals also contribute to heart and lung disease, including in those exposed to second-hand smoke. Consequently, cigarettes remain the only consumer product that, when used as intended, will kill half of all long-term users.

All of this has been known for decades. Yet for decades, nothing changed. The cigarette industry remained intact, continuing to addict and kill off its consumers year after year after year. Then, our product was created. Our product was specifically developed to provide adult smokers with a familiar nicotine experience to transition them from combustible use and, ultimately, eliminate cigarette consumption.

Quitting nicotine consumption altogether may be the preferred outcome for many public-health advocates. But nicotine is addictive—and quitting nicotine is hard. Adult smokers need a viable alternative to cigarettes that drives them away from combustible use to a less harmful nicotine delivery system. Vapor products, like ours, can fill that void through a technology that, while containing nicotine, does not produce the thousands of combustion-related constituents linked to smoking-related diseases. Simply put, vapor products represent an unprecedented and generational harm-reduction opportunity for adult smokers.

Former FDA Commissioner Scott Gottlieb has explained that nicotine “is not directly responsible for the tobacco-caused cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year.”³ And the FDA’s 2018 Strategic Policy Roadmap asserts that “[i]t is the other chemical compounds in tobacco, and in the smoke created by setting tobacco on fire, that directly and primarily cause the illness and death – not the nicotine.”⁴ Public Health England has concluded that e-cigarettes are approximately 95% safer than combustible cigarettes.⁵

Yet we are keenly aware that this unprecedented public-health opportunity will be undermined unless we collectively reverse the trend in youth use. We see the same data, and read the same reports, that speak to an unacceptable increase in youth use. Youth use cannot go unabated. That is why we have taken significant and aggressive actions to address youth access, appeal, and use of our products. And we will do more and will continue to advocate for category-wide measures to reduce youth use of *all* vapor products.

³ See Gottlieb, Scott & Zeller, Mitchell, *A Nicotine-Focused Framework for Public Health*, 377 NEW ENG. J. OF MED. 1111, Sept. 21, 2017, <https://www.nejm.org/doi/full/10.1056/NEJMp1707409>.

⁴ *Healthy Innovation, Safer Families: FDA’s 2018 Strategic Policy Roadmap*, FDA, Jan. 11, 2018, <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM592001.pdf>.

⁵ See Brose, McNeil, et al., *E-cigarettes: an evidence update, A report commissioned by Public Health England*, August 2015, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/733022/Ecigarette_s_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf.

I. Our Mission: Leading and Accelerating an End to Combustible Cigarettes

Over fifteen years ago, our co-founders, Adam Bowen and James Monsees, both of whom smoked cigarettes at the time, became convinced that the cigarette industry needed disruption.⁶ Many smokers wanted to quit, they knew, but could not do so without finding another way to satisfy their need for nicotine. Yet no alternatives on the market appealed to adult smokers. For many, traditional nicotine therapies such as patches, gum, and lozenges were not effective. Indeed, studies have found that less than 10% of smokers who use these products successfully abstain from combustible cigarettes.⁷ Without a satisfying nicotine alternative, many smokers continued to fail in their efforts to stop smoking and continued to return to a product they knew would cause them to suffer a premature fate.

Adam and James then created the JUUL device. The product was designed for the adult smoker—an alternative nicotine delivery system, without the thousands of harmful chemicals associated with combustible tobacco use. The design was intended to: (i) end the perpetuation of cigarette iconography and the “round, white stick”; (ii) actually appeal to adult smokers; and (iii) create an operationally sound and consistently performing product compared to other vapor products or e-cigarettes. Nicotine strengths matter—our products’ nicotine concentrations provide adult smokers with a similar satisfaction to combustible cigarettes, which helps facilitate their switch. And our products’ relatively small number of responsible flavors play a critical role in keeping adult smokers from cigarettes, including non-traditional flavors that offer adult smokers an alternative to the taste of burning tobacco.

While additional long-term research is needed to assess the individual and net public-health effects of vapor products over time, products like ours offer an immediate opportunity to move adult smokers down the continuum of risk associated with tobacco use.

We are starting to see the positive health effects of vapor products in our own data. For example, in a recent clinical study of adult smokers, which assessed biomarkers of exposure (“BOEs”) linked to tobacco-related cancers and heart and lung disease, the data showed equivalent

⁶ See *Our Founders’ Story*, JUUL, Feb. 27, 2019, <https://newsroom.juul.com/2019/02/27/our-founders-story/>.

⁷ See, e.g., Hajek, Peter, et al., *A Randomized Trial of E-Cigarettes versus Nicotine Replacement Therapy*, 380 NEW ENG. J. OF MED. 629, Feb. 14, 2019, <https://www.nejm.org/doi/full/10.1056/NEJMoa1808779> (finding that 9% of study participants using nicotine replacement therapy devices other than e-cigarettes had abstained from smoking); Moore, David, et al., *Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis*, 338 BMJ Jan. 14, 2009, <https://www.bmjjournals.org/content/338/bmj.b1024> (finding that 6.7% of smokers using nicotine replacement therapy devices other than e-cigarettes attained sustained abstinence from cigarettes for six months).

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reductions between JUUL product users and smoking abstainers.⁸ The study—a randomized, open-label, parallel group, five-day inpatient assessment—examined changes, relative to baseline, in primary urine and blood BOEs in 90 adult smokers. The selected short-term biomarkers were carcinogens and toxicants observed in the use of combustible cigarettes. Study subjects were randomized into six groups that, over five days, used JUUL products, abstained from smoking, or continued use of their usual brand of cigarettes. Before the baseline reading, subjects abstained from smoking for twelve hours to assess BOE impact across the three groups.

The study found that all eight non-nicotine urine BOEs were reduced by an aggregate of 85.3% in the abstinence group compared to an aggregate of 85% in the JUUL product group.⁹ This represented a 99.6% relative reduction in aggregate BOEs for the JUUL product group. In the cigarette group, the same BOEs increased by an aggregate of 14.4% from baseline.¹⁰

We also are seeing the net-population impact and effect of our products to switch adult smokers from combustible cigarettes at unprecedented rates. One study, published in the *Harm Reduction Journal*, included a non-probabilistic sample of 15,456 U.S. adult smokers (21+) who purchased JUUL products either at retail stores or online through JUUL.com.¹¹ Survey participants were assessed at monthly intervals over three months to determine use rates, use patterns, and past 30-day smoking history. The final follow-up assessment was conducted after three months of JUUL product use.

Based on the entire survey sample, 28.3% of JUUL product users had completely abstained from smoking cigarettes in the 30 days prior to the final three-month follow-up assessment. Of those users who completed the three-month follow-up assessment, 47.1% of JUUL product users had completely abstained from smoking cigarettes in the 30 days prior. The study further found that participants who had exclusively used non-tobacco flavors (Mango, Cucumber, Fruit, Creme, Menthol, and Mint) were 30% more likely to have abstained from smoking at three months compared to those who exclusively used tobacco flavors.¹² In addition to being the most commonly used flavors, smokers who primarily used Mint or Mango JUULpods in the 30 days prior to the 3-month assessment were 37% and 26% more likely, respectively, to have not smoked

⁸ See Jay, Joanna, et al., *Changes in Biomarkers of Exposure Associated with Switching for 5 Days from Combusted Cigarettes to Nicotine Salt Pod System*; Poster Presented at the 2019 Society for Research on Nicotine and Tobacco Annual Conference, Feb. 23, 2019..

⁹ *Id.*

¹⁰ *Id.*

¹¹ See Christopher Russell, et al., *Factors Associated with Past 30-day Abstinence from Cigarette Smoking in a Non-Probabilistic Sample of 15,456 Adult Established Current Smokers in the United States Who Used JUUL Vapor Products for Three Months*, HARM REDUCTION JOURNAL (2019). This and other studies are available for scientific review and assessment at <https://jliscience.com>.

¹² *Id.*

any cigarettes in the previous 30 days compared to primary users of Virginia Tobacco flavored JUULpods.¹³

Additionally, we are beginning to see the sustained impact of our products on the cigarette market. As the sales volume of JUUL products, as measured as a percentage of the U.S. combustible cigarette market, has grown since 2018, cigarette-pack sales volumes continue to decline at accelerated rates. In the past two four-week reporting periods based on syndicated market data, cigarette-pack sales volumes have faced year-to-year declines of 8% or more. For the period ending in late March, year-over-year declines for cigarette-pack sales volumes were 8.8%.

In geographic areas where JUUL products have high market penetration, cigarette-pack sales volume declines are even more pronounced. In our top five syndicated cities as measured by Nielsen—New York City, Portland, Oklahoma City and Tulsa, Seattle, and Denver—declines accelerated from 3.8% year-over-year one year ago to 9.9% year-over-year in the latest reporting period. More broadly, the data suggest a negative correlation between JUUL products and cigarette-pack sales volumes: in the top 25 U.S. cities measured by Nielsen, as sales of JUUL products increased, sales of cigarettes fell.¹⁴

These data drive us every day. We will continue to engage the FDA, other government stakeholders, and the public health community to lead the dialogue around the harm-reduction potential of our products.

II. Our Actions to Address Youth Access, Appeal, and Use of JUUL Products

Since May 2018 when we met with the FDA to discuss our initial youth-prevention efforts, we have been actively engaged with the FDA to address the issue of youth use of vapor products. During that meeting, we highlighted some of our ongoing initiatives, including our secret-shopper program and aggressive takedowns of third-party social-media content, as well as our advocacy for Tobacco 21 laws. In November 2018, in response to the Agency's call to action, we undertook more comprehensive actions, effectively resetting how we market and sell our products to combat youth use.

With our action plan to address youth access, appeal, and use of JUUL products, we, as the market leader, saw the need to take swift and significant measures. Our efforts included:

¹³ *Id.*

¹⁴ Market analyses provided herein were developed from syndicated market data provided by The Nielsen Company's "Answers on Demand Services for the Total Store/Tobacco Category."

- Suspending the distribution of non-tobacco and non-menthol-based (“NTM”) flavored JUUL products to over 90,000 traditional retail outlets;¹⁵
- Enhancing our ecommerce platform, which utilizes third-party 21+ age-verification and bulk-purchasing limits, with two-factor authentication and facial-recognition technology for uploaded I.D.s;
- Improving retailer compliance by expanding our secret-shopper program to 2,000 stores per month to check retailers for compliance with federal age-verification and company-specific bulk-purchasing requirements;
- Exiting U.S. Facebook and Instagram accounts and retaining Twitter only for non-promotional communications; and,
- Building end-to-end traceability for JUUL products to identify where they are being sold to youth and developing a next-generation product with user-level access restrictions that could potentially prevent youth use.

We actively support raising the minimum purchasing age for all tobacco products, including vapor products like ours, to 21 years of age. Social sourcing—when a legal-age purchaser provides the product to an underage user—continues to be the main driver in youth access and use. Approximately 70–80% of youth use of vapor products comes from social sourcing.¹⁶ Based on the 2017 Youth Risk Behavior Survey, only 13.6% of high school students (aged 17 years or younger) obtained a vapor product from a brick-and-mortar retail outlet, while 6.7% obtained a vapor product online. The 2018 National Youth Tobacco Survey tells a similar story: 58% obtained the product from a friend, 6.8% obtained the product from a family member, and 6.6% obtained the product from another person.¹⁷ Tobacco 21 laws are the quickest and most effective measure to address this issue.

Since January 2019, six more states have passed such legislation, bringing the national total to twelve states, representing more than one third of the U.S. population. Several other states are considering their own proposals, and JLI is actively supporting those efforts through public-affairs campaigns, written and in-person testimony, and by drafting legislation.

The most meaningful action, however, can come from this Congress to raise the minimum purchasing age for tobacco products, including vapor products like ours, to 21 nationwide. We

¹⁵ Currently, the Company sells its NTM flavored products only through JUUL.com, which incorporates automated, multi-step technologies to ensure purchasers are 21+ regardless of jurisdiction and limits the amount of product that can be purchased.

¹⁶ See Center for Disease Control and Prevention, 2017 Youth Risk Behavior Survey.

¹⁷ See Center for Disease Control and Prevention, 2018 National Youth Tobacco Survey.

are encouraged by the fact that numerous Tobacco 21 bills have been introduced. JLI will continue its public advocacy to support those bills and other measures that will effectively reduce use of vapor products by underage users.

We will continue to lead our industry in undertaking innovative efforts to eliminate youth use. We recognize that JLI cannot fulfill its mission to eliminate cigarette use by adult smokers so long as youth use goes unabated. We have acted and will continue to do so because it is the right thing to do and because we must preserve this generational opportunity to drive adult smokers away from the very product that will kill them.

III. Altria: An Opportunity to Reach Additional Adult Smokers

We understand that some see Altria as an unlikely—and seemingly counterintuitive—investor in a Company committed to eliminating combustible cigarettes. As we have said before, we understand the controversy and skepticism that comes with our affiliation with the largest tobacco company in the United States. We, too, were initially skeptical. But as a condition of investing in our Company, Altria met demanding and specific criteria to ensure the continued achievement of our goal. Specifically, prior to the investment, we made it clear that:

- An investor would have to adopt and support our mission. Altria did that and stated: “We are taking significant action to prepare for a future where adult smokers overwhelmingly choose non-combustible products over cigarettes by investing \$12.8 billion in JUUL, a world leader in switching adult smokers. We have long said that providing adult smokers with superior, satisfying products with the potential to reduce harm is the best way to achieve tobacco harm reduction. Through JUUL, we are making the biggest investment in our history to achieve that goal. We strongly believe that working with JUUL to accelerate its mission will have long-term benefits for adult smokers and our shareholders.”
- An investor would have to back up its commitment with tangible actions and real value outside of its financial investment. Altria did that by agreeing to provide us services that will accelerate our ability to get JUUL products in the hands of adult smokers:
 - Altria will provide JLI access to Altria’s premier tobacco products retail shelf space, allowing JUUL’s tobacco and menthol-based products to appear alongside combustible cigarettes.
 - Altria will enable JLI to reach adult smokers with direct communications through cigarette pack inserts and mailings to adult smokers via Altria companies’ databases.

Moreover, as part of this investment, JLI remains fully independent and retains full operating control. Altria is subject to a standstill agreement that will not allow it to acquire additional shares above its current 35% level.

Thus, our relationship with Altria furthers our efforts to help adult smokers make the switch from combustible cigarettes.

* * *

We are fully committed to our goal and our values. Our success ultimately depends on our ability to get our product in the hands of adult smokers and out of the hands of youth. When adult smokers try it, it works. And the impact is life-changing.

IV. Responses to Specific Questions Set Forth In Your Letter

- 1. FDA Commissioner Gottlieb has said that approximately two-thirds of JUUL users are “new users of nicotine”—meaning, on an overwhelming basis, your products are not being used by adult smokers as a smoking cessation device. Has JUUL ever conducted a clinical trial in the United States proving that its products actually help smokers quit? If so, please provide that study. If not, why not?**

Response:

Based on the Company’s behavioral research, a very small portion of JUUL users have not previously used a nicotine product (either cigarettes or vapor products). For example, in one published study, funded by JLI, which included 18,799 survey respondents of JUUL users, 90.2% of participants had used nicotine through the use of cigarettes and/or vapor products before their first ever use of JUUL products. Only approximately 6.9% of participants had never smoked a cigarette or used a vapor product before their first use of JUUL products.

Two recent behavioral studies JLI funded indicate that using JUUL products helps smokers switch from combustible cigarettes.

The *Harm Reduction Journal* published one of the studies: “Factors Associated with Past 30-day Abstinence from Cigarette Smoking in a Non-Probabilistic Sample of 15,456 Adult Established Current Smokers in the United States Who Used JUUL Vapor Products for Three Months.” As described above, of the study participants who completed the three-month follow-up assessment, 47.1% of JUUL product users had completely abstained from smoking cigarettes in the 30 days prior.¹⁸

¹⁸ Christopher Russell, et al., *Factors Associated with Past 30-day Abstinence from Cigarette Smoking in a Non-Probabilistic Sample of 15,456 Adult Established Current Smokers in the United States Who Used JUUL Vapor Products for Three Months*, HARM REDUCTION JOURNAL (2019). This and other studies are available for scientific review and assessment at <https://jlisience.com>.

The *Journal of Pulmonary and Respiratory Medicine* published the other study: “Vaping and the Number of Cigarettes Not Now Smoked: An Additional Means of Assessing the Public Health Impact of E-cigarettes.” This study found “a substantial reduction in the quantity of cigarettes smoked from baseline to three months amongst a sample of adult smokers using the JUUL e-cigarette.”¹⁹

All three of these studies are enclosed with this letter.

JLI has continued to develop follow-up assessments of adults enrolled in the behavioral studies cited above, in order to understand the long-term changes in smoking behavior. Among 5,657 established baseline smokers who have completed nine-month follow-up assessments thus far, 58.4% of JUUL product users had completely abstained from smoking cigarettes in the 30 days prior. Critically, past-month abstinence from smoking cigarettes has been increasing at each follow-up assessment, in contrast to the patterns of relapse to smoking that are observed among long-term users of available NRTs. The Company will continue to develop and support these types of behavioral studies that assess smoking behavior among adult users of JUUL products to the one year mark, for eventual publication in peer-reviewed journals.

- 2. The 2016 NYTS found that 78.2 percent of middle- and high-school students—20.5 million youth—had been exposed to e-cigarette advertisements from at least one source.**
 - a. Please provide a list of all of JUUL’s advertising buys—including radio, TV, print, and social media.**
 - b. What steps has JUUL taken to ensure that these advertisements are not seen or heard by people under the age of 21?**
 - c. Altria and other Big Tobacco companies, are prohibited from airing TV and radio advertisements for cigarettes and—under the Master Settlement Agreement—cannot run advertisements for cigarettes in publications with a substantial youth readership. Going forward, will JUUL commit to not airing any TV, radio, print, or social media e-cigarette advertisements that could be viewed by people under the age of 21?**

Response:

All of JLI’s advertisements are intended to encourage adult cigarette smokers to make the switch to our products.

¹⁹ McKeganey, Neil, et al., *Vaping and the Number of Cigarettes Not Now Smoked: An Additional Means of Assessing the Public Health Impact of E-cigarettes*, J. PLUM RESPIR MED 3: 104, 2019, https://docs.wixstatic.com/ugd/c53053_ba12ea65795a4353be31ba48c98bccde.pdf.

JLI has taken a number of steps to ensure its advertisements reach their intended audience of adult smokers. The Company's advertising currently features only adult smokers who have used JUUL products to switch from combustible cigarettes. The Company also has developed testimonials featuring adults who have successfully switched from combustible cigarettes to JUUL products. The individuals in these testimonials are real consumers—not models or professional spokespeople. And every testimonial thus far has been from an adult between the ages of 29 and 74.

We also run our advertisements in media with very low youth exposure. On radio, for example, we advertise on stations with at least 85% listenership over 21, the strictest available standard. As another example, some of our early television advertisements were run during late-night reruns of *The Golden Girls* and were run on other programs with more mature viewers.

Further, as discussed above, JLI recently exited its U.S. Facebook and Instagram accounts and limited its Twitter account to non-promotional communications. Further, in July 2018, the Company launched a newspaper, digital, and radio educational campaign, entitled "What Parents Need to Know About JUUL," to help raise awareness about youth use and prevention.

The Company's advertising is intended to encourage adult cigarette smokers to make the switch to JUUL products. Advertising therefore plays an important role in the Company's efforts to reduce the number of smokers in the United States. If current adult smokers are not aware of JUUL products, they will not use JUUL products to help them make the switch from combustible cigarettes. Thus, increasing smokers' awareness of JUUL products through advertisements goes hand-in-hand with the Company's goal of improving the lives of the world's one billion adult smokers.

3. According to the CDC, nearly 7 in 10 youths—17.7 million children—were exposed to e-cigarette advertising in retail stores in 2016. Will JUUL commit to not advertising in convenience stores or other retail stores, where advertisements can be widely viewed by children?

Response:

JLI's advertising is directed at current adult smokers and attempts to persuade those smokers to switch from combustible cigarettes. Displaying JUUL products in close proximity to combustible cigarettes increases the probability that current adult smokers will choose JUUL products over combustible cigarettes. Further, as discussed above, data indicate that the vast majority of youth who gain access to vaping products do so through social sources—not through purchases at retail stores.

Nevertheless, the Company acknowledges the critical need for retail outlets to implement strict compliance measures that ensure youth cannot access JUUL products. The discussion above

detailed the many steps the Company has taken to ensure retail stores prevent youth access to its products. For additional information on our efforts to enhance compliance at retail stores, please see the answer to question 7(b).

- 4. Has JUUL paid any “social media influencers” to promote its products? If so, please provide a complete list of influencers who have been paid by JUUL to promote its products. Has JUUL identified its connection with these influencers, in accordance with Federal Trade Commission (FTC) rules?**

Response:

JLI does not currently pay any “social media influencers.” Since the Company’s inception, only six individuals, each of whom was a smoker or former smoker age 28 or older, have been paid to post social-media content related to JUUL products. Combined, JLI paid all six influencers less than \$10,000.

- 5. Please list all new contracting, purchasing order, and other financial arrangements with retailers, wholesalers, and distributors for JUUL products since the December 19, 2018 Altria announcement.**

Response:

As discussed above, JLI’s relationship with Altria furthers the Company’s goal of helping smokers switch from combustible cigarettes. JLI is an independent operating company and we continue to have our own relationships. The real change in our relationships consists in the use of Altria services to further reach adult smokers.

- 6. Please provide a copy of JUUL’s response to the FDA’s 904(b) letter on April 24, 2018.**

Response:

We submitted this information as part of our ongoing conversations with the FDA, but please note that much of the information is included here in response to your related questions.

- 7. In response to FDA’s September 12, 2018, letter requesting a plan to address the epidemic of youth e-cigarette use, JUUL announced on November 13, 2018, that it will, among other actions: shut down its Facebook and Instagram accounts; stop accepting retail orders for Mango, Fruit, Crème, and Cucumber JUULpods in specialty vape shops and convenience stores; and enhance its online sales age-verification process and technology. In its own response, Altria committed to, among other policies and actions, discontinuing sales of its flavored e-cigarette products.**

- a. Following the December 19, 2018, Altria merger announcement, please list any and all changes to JUUL's November 13, 2018, commitments and action plan.

Response:

Altria's investment changed absolutely nothing about JLI's commitment to implementing its November 2018 youth action plan. The Company's actions demonstrate this. Since November 2018, the Company has implemented the steps outlined in its plan and, in some instances, has taken further steps in support of stopping youth use of e-cigarettes.

Please note that JLI and Altria did not merge. As discussed above, Altria invested in JLI in exchange for a 35% minority ownership interest in the Company. As part of the transaction, Altria entered into a standstill agreement that prohibits it from acquiring additional shares in the Company. Accordingly, the investment did not affect JLI's operational control of the business.

- b. JUUL indicated that, in the future, it would "re-start accepting orders" for flavored JUULpods from stores that "comply with the criteria of our new 21+ Restricted Distribution Program."
 - i. Which retail outlets would be eligible for participation in this new program and when would they be able to sell flavored JUULpods?
 - ii. What criteria will JUUL use to determine the adequacy of age-verification technology implemented by retail outlets? Will JUUL use an independent third party entity to verify the adequacy of retail store actions? Will JUUL notify and/or work with the FDA to ensure the adequacy of this system?
 - iii. What is the expected timeline for retail outlets to become compliant in such a system?

Response:

Youth access is driven by a lack of age verification and, more often, social sourcing in which a friend, family member, or peer of legal age purchases or furnishes the product to youth. To address these gaps contributing to youth access and use, the Company established its 21+ Restricted Distribution System ("21+ RDS") for the sale of NTM flavored JUUL products—a system premised on automated sales controls to restrict access to adults 21+ and prevent bulk purchases. At the outset, please note that the Company currently sells NTM flavors only through its strictly controlled online portal.

21+ RDS is a point-of-sale ("POS") system that would be automated to require multiple steps of age and identity verification, with a bulk-purchasing control to limit the amount of product

that can be purchased. If a customer attempted to purchase an NTM flavored product in a retail outlet with 21+ RDS, the product would be identified as “restricted.” To proceed in the transaction, the retail clerk would be required to scan the customer’s I.D. to ensure he or she is at least twenty-one years of age (regardless of jurisdiction) and validate that the I.D. has not expired. This scan also would pull information from the I.D.’s barcode and temporarily display that information on the POS screen, so that the retail clerk could verify that it matches what is presented on the physical I.D. to reduce potential fraud. The POS system would also limit purchases to two JLI devices and/or five JUULpod packages per transaction (regardless of which flavors are purchased). If the transaction did not pass the above requirements, the system automatically would block the sale: there would be no override option.

Currently, the Company sells NTM flavored products only through its ecommerce platform, where it uses automated, multi-step technologies to ensure purchasers are 21+ and prevents bulk purchases. JLI has no current plans to reintroduce NTM products to traditional retail stores, and it will only do so after it verifies that retailers have implemented 21+ RDS. This verification process would conceptually occur in three stages:

First, retailers would apply for certification and be assessed against JLI’s 21+ criteria. As noted above, they would be required to comply with strict POS requirements to ensure limited and controlled access to NTM flavored products for adults 21+. A retailer would submit an application to the Company and be assigned an RDS manager to complete the preliminary review. The retailer then would be inspected and verified in-store against JLI’s 21+ RDS criteria, effectively testing the POS system through *bona fide* transactions. Following the qualification period, the retailer would (or would not) be certified to sell NTM flavored products. Any retailer, including convenience stores and independent specialty vape shops, would be eligible to apply and be certified against JLI’s 21+ RDS if they met the criteria.

Second, retailers and their employees would be required to complete compliance training on 21+ RDS requirements. JLI would prepare the educational materials and coordinate with the retailer to establish a robust training program. Each employee would be required to complete 21+ RDS training, and the retailer would provide proof of completion.

Third, 21+ RDS-certified retailers would be subject to periodic and ongoing compliance checks to verify continued adherence to 21+ RDS criteria. The Company would utilize a third party to conduct compliance checks (i.e., “secret shoppers”). If a retailer were to fail, it would be required to provide a remediation plan and ultimately could be excluded from JLI’s 21+ RDS.

JLI continues to test the technical feasibility of this closed, automated POS system to restrict youth access, and it believes such technological enhancements and POS upgrades could be implemented widely.

- c. **Ostensibly to prevent bulk shipments and youth access, JUUL announced that it would limit online customers to two devices and fifteen JUUL pod packages per month, and no more than ten devices per year.**
 - i. **Will JUUL notify and/or work with the FDA to ensure the adequacy of this system?**
 - ii. **How did JUUL determine it would limit online purchases to 15 JUUL pods per month? Please provide pattern of use documentation to explain.**
 - iii. **For products sold online, will JUUL require independent, third-party age and identity verification that compares customer information against third-party data sources, such as public records?**

Response:

JLI's ecommerce platform utilizes industry-leading technology to ensure purchasers are 21+ regardless of jurisdiction and to limit the amount of JUUL products that can be purchased monthly. Before the Company submitted its action plan to the FDA in November 2018, to complete a purchase on JUUL.com, the customer was required to create an online account that passed the following checks:

- *Public records match:* The consumer had to input name, date of birth, address, and the last four digits of his or her social security number. JLI's social-security-number requirement created a barrier to youth access that was unusual in this industry and made it significantly more difficult for someone underage to use an adult's address and credit card information to complete a purchase. The consumer could opt out of the social-security-number requirement but was then required to upload a government-issued identification for verification. The consumer's personal information was verified by a qualified third party and referenced across publicly-available records to confirm that the consumer was at least 21 years of age.
- *Manual upload of government-issued identification:* If the public records search failed, or the consumer opted out of entering his or her social security number, the consumer had to upload a government-issued identification. A member of JLI's trained in-house compliance team reviewed the identification against reference materials and approved or rejected the purchase.
- *Personal information locks and additional fraud checks:* During the checkout process, the system locked the consumer's age-verified name. The consumer could not use a different name in either the credit card, billing address, or shipping address sections. In addition, every order placed on the JUUL.com system was filtered through a third-party fraud

detection platform, which checked transaction details (e.g., address, credit card information, device identification, and IP address) against a known and expanding blacklist, as well as an evolving set of fraud-protection rules that automatically blocked suspicious transactions.

As part of our action plan, we committed to further enhance JUUL.com's age-verification processes. Among other things, the Company now requires the consumer to provide his or her phone number for two-factor authentication to verify identity and as an additional data point cross-referenced during the public records check. For two-factor authentication, the consumer's phone number receives a code that requires input on JUUL.com to verify the account before proceeding to purchase. The Company applies this requirement for all newly created ecommerce accounts, as well as a retrospective application for previously created accounts. JLI also has incorporated facial recognition technology for uploaded IDs to prevent fraud. A consumer subject to the manual upload process is required to upload a "selfie" that is analyzed by a third party to verify that the photograph matches the consumer's government-issued identification. This technology also utilizes programmed algorithms to identify potential fake identification. JLI no longer uses its internal compliance team as part of the manual identification upload process.

JLI also committed to the FDA to conduct an audit of its age-verification system. The Company engaged multiple third-party firms to administer the audit, including the recruitment of individuals, aged 18–20 years, to test JLI's 21+ age-verification system. These individuals are of legal age in the jurisdiction where they reside. Over 100 individuals participated in the program thus far across the audits, with none successfully defeating our age verification system. The audit remains ongoing and, based on the final report, JLI will assess whether additional enhancements are appropriate. The Company has informed the FDA of this audit process and will provide a final report as part of its action plan commitments.

In addition to its age-verification system, the Company has established bulk purchasing limits based on reasonable individual consumption of JUUL products. Consumers are limited to two JUUL devices and fifteen JUULpod packages per month (60 JUULpods per month), and a maximum of ten JUUL devices annually. If the consumer tries to exceed these bulk limits, the system cancels the transaction. The Company established these limits, particularly those for JUULpod packages, based on cigarette consumption patterns of heavy smokers, who may smoke two packs per day. Generally speaking, one JUULpod is approximately equivalent to one pack of cigarettes.

8. Did JUUL, or any of its employees or contractors, discuss with Altria, or any of its employees or contractors, either company's response to the FDA's September 12, 2018, inquiry on plans to address youth e-cigarette use?

Response:

To the best of my knowledge, JLI and Altria did not communicate directly or through employees, consultants, or contractors about their respective responses to the FDA's September 12, 2018 inquiry prior to submission.

9. Please provide a breakdown of sales—broken down by retail and online—between all of JUUL's flavored products—including year-over-year sales, aggregate sales, and percentage sales between flavored JUULpods.

Response:

The information requested is competitively sensitive. That said, we note that, prior to JLI removing flavored JUULpods from retail stores in order to prevent youth access to such products, approximately 90% of authorized sales of JUUL products occurred through authorized resellers or retailers, while less than 10% of authorized sales occurred through JLI's ecommerce website (JUUL.com).

Further, in 2018 NTM flavors were 41.55% of the units sold in retail stores. In 2019 year to date, NTM flavors were 8.12% of the units sold in retail stores.

10. Has JUUL collected information on the appeal of its flavored products among youth? Please provide information on youth use of each of JUUL's flavored products.

Response:

In August 2018, JLI met with FDA to discuss youth-focused behavioral research to better understand the scope of youth use of vapor products generally, JUUL products specifically, and combustible cigarettes, among other tobacco products. Since then, the Company has executed two separate studies on youth prevalence and youth perception, respectively. The studies have been designed, run, and controlled by an independent research organization. The Company's role was limited to funding the studies. JLI does not have access to the raw data and has not exerted control over the research. JLI intends to use this research as part of its pre-market tobacco product application ("PMTA") for the current JLI system.

11. As you know, under the Tobacco Control Act, no new tobacco product can be legally marketed unless FDA has granted an order permitting such marketing. The FDA's 2016 deeming rule extended this authority to e-cigarettes and set an effective date of August 8, 2016—meaning a product that was not on the market as of that date may not be sold without an FDA marketing order.

a. Has FDA issued a pre-market order to any JUUL product?

Response:

To date, the FDA has not issued a pre-market order to any JUUL product.

- b. When the FDA's Tobacco Product Listing database was accessed on August 27, 2018, there were 278 total JUUL products listed, including 57 distinct flavors in three distinct nicotine levels (0.5%, 3%, 5%) and categorized as both e-liquids and ENDS cartridges (5% 2.8mL/pk). These flavors included: Apple Cinnamon, Apple Cran, Apple Tart, Arctic Lime, Banana Crème, Berry, Berry Tart, Black Flag Risen Enriched, Blueberry Citrus, Bowden's Mate, Chamomile Tea, Chestnut Croissant, Chocolate Mint, Cinnamon Beignet, Cinnamon Spice, Cinnamon Tart, Citrus Medley, Coco Mint, Coconut Bourbon, Elderflower Fizz, Ginger Peach, Grapevine, Guava Lychee, Kiwi, Lemon Tart, Lemon Tea, Mimosa, Old Fashioned, Pear Tart, Spicy Watermelon, Strawberry, Strawberry Limoncello, Strawberry Rhubarb, Thai Tea, Tropical Melon, and Watermelon Limon.**
 - i. When did JUUL submit these 57 distinct flavors to FDA for registration and listing?**
 - ii. On what date did each of these 57 distinct flavors and three nicotine levels first appear on the market? Specifically, for each flavor and nicotine level combination, when did the first retail purchase order and online transaction occur?**
 - iii. Please provide the first date that free samples were distributed, if applicable, for each of the 57 flavors and three nicotine levels.**

Response:

Flavors are a complex issue. JLI believes flavors play a critical role in switching adult smokers from cigarettes; we see the results in our own behavioral research. While JLI does not and will not sell flavors which are clearly targeted to youth, it also understands that flavors that drive adults from cigarettes have the potential to appeal to youth. To strike the right balance between preserving accessibility for adult smokers, while restricting access for youth, JLI stopped the distribution of NTM flavored JUULpods to traditional retail. Currently, JLI sells these flavored products only through its ecommerce platform (JUUL.com), where it utilizes industry-leading third-party age-verification and restricts bulk purchases.

In June 2015, JLI launched the JUUL device and four JUULpod flavors at 5% nicotine strength—Virginia Tobacco, Cool Mint (now Mint), Fruit Medley (now Fruit), and Creme Brulee (now Creme). These products were actively marketed and sold through various sales and distribution channels, including traditional convenience stores and independent outlets. From

December 2015 to January 2016, JLI expanded its JUULpod product portfolio to include additional e-liquid flavors and nicotine strengths (e.g., 0.5%, 1.7%, 3.0%, and 5.0%). These products were sold through a limited number of independent, specialty vape shops.

In August 2016, before the August 8, 2016 deeming date, JLI again expanded its JUULpod product portfolio to include additional e-liquid flavors and nicotine strengths. Similar to the December 2015 to January 2016 product expansion, these products were sold through a limited number of independent, specialty vape shops.

The JUULpod flavors of the initial launch (June 2015) and subsequent product expansions (December 2015 to January 2016 and August 2016) are what was represented in the Company's product listing that was submitted to the FDA by October 30, 2017. Beyond JLI's current JUULpod product offerings (Virginia Tobacco, Classic Tobacco, Menthol, Mint, Mango, Fruit, Cucumber, and Creme), the Company has not marketed or sold the products referenced above, or from its initial product listing, since the product expansions in December 2015 to January 2016 and August 2016. Moreover, as part of its August 2016 launch, many of the flavors referenced above, and included in its product listing with the FDA, were "partner flavors"—flavors that were purchased from a third party and combined with JLI's proprietary e-liquid formulation and marketed under the "JUUL" product name. To be clear, some of the flavor names reflected as part of JLI's initial product listing were *not* the Company's names. Rather, they were the flavor names as marketed by the third-party vendors (pre-JUUL formulation), but under the "JUUL" brand. JLI has no intention of re-launching those products in the U.S. market.

JLI is unaware of any "free samples" relating to products from the December 2015 to January 2016 and August 2016 product expansions. Since the deeming rule's effective date of August 8, 2016, JLI has implemented policies prohibiting free samples consistent with the FDA's regulations.

We support the FDA's draft guidance restricting the sale of certain flavored products, including JUULpods, at retail outlets and online.

c. When the FDA's Tobacco Product Listing database was accessed on January 16, 2019, there were only 52 products listed.

- i. When did JUUL de-register the previously listed products from the FDA database?**
- ii. When and why were the previously listed products removed from the market?**

Response:

Following the FDA's inspection of JLI's headquarters in September 2018 and after consulting with the FDA inspectors, the Company "de-listed" all of the products previously

included in its initial product listing submission. Under the Family Smoking Prevention and Tobacco Control Act (“TCA”), only manufacturers of a tobacco product, as defined, are required to register with the FDA and list the products that are being manufactured for commercial distribution. *See TCA, § 905(i)(1).* By statutory definition, JLI does not actually own or operate any establishment that manufactures tobacco products; rather, it relies on a well-controlled network of contract manufacturers for each step of the manufacturing process. As a result, JLI was not the appropriate entity to list JUUL products, including the products previously listed in its initial submission to the FDA by October 30, 2017. Moreover, because the products are not currently marketed, they are not required to be listed by any manufacturer.

By October 2018, and following a discussion with the FDA personnel during an inspection of our headquarters, JLI revised its registration and listing with the FDA to provide better clarity on which establishments are currently manufacturing JUUL products. The current product listing reflects the products that are currently being manufactured by the Company’s contract manufacturers for commercial distribution in the United States.

- d. **Among the 52 products described in (10)(c) are five e-liquid flavors—Classic Menthol, Cool Cucumber, Fruit Medley, Mango, and Mint, in “0.5 salt” concentrations. Additionally, there are “JUUL Compatible Private Blend Refill Kits” in multiple nicotine concentrations and sizes (0.0%, 1.7%, 3%, 5% and both 2.8mL/pk and 4mL/pk).**
 - i. **When did JUUL submit each of these distinct products to FDA for registration and listing?**
 - ii. **On what date did each of these products first appear on the market? Specifically, when did the first retail purchase order and online transaction occur for each of these distinct products?**
 - iii. **Please provide the first date that free samples were distributed, if applicable, for each of these distinct products.**

Response:

Please see response to 11(b).

- e. **On July 12, 2018 JUUL Labs announced that it would offer 3% nicotine pods in Mint and Virginia Tobacco flavors, noting these 3% nicotine pods would be available in “limited quantity” in August 2018 and “widely available” in October 2018. In March 2019, JUUL announced that it was making its Mango, Fruit, Crème, and Cucumber pods available in 3% strength as well. The announcements appear to indicate new products entering the market without pre-market orders from the FDA.**

- i. On what date did each of these 3% nicotine pods first appear on the market?
- ii. Specifically, when did the first retail purchase order and online transaction occur for each of these products?

Response:

Please see response to 11(b). Specifically, for JUULpod flavors Virginia Tobacco and Mint at 3% nicotine strength, these products first appeared on the market as part of the December 2015 to January 2016 product expansion and were also part of the August 2016 product expansion. For JUULpod flavors Mango, Fruit, Creme, and Cucumber at 3% nicotine strength, these products first appeared on the market as part of the December 2015 to January 2016 product expansion.

12. According to a recent report, JUUL has an “enterprise markets team” that is working to strike deals with health insurers, employers, health care providers, and the public sector to make JUUL available to employees and beneficiaries who want to stop smoking cigarettes.
 - a. What data and other information does JUUL communicate to health insurers, employers, health care providers, and the public sector about whether JUUL is effective at helping adult smokers stop smoking cigarettes?
 - b. Does JUUL clearly indicate that its products have not been found to be safe and effective by the FDA for the purpose of smoking cessation?
 - c. Please provide copies of materials that JUUL provides to health insurers, employers, health care providers, and the public sector.
 - d. Please provide all documents and other information reflecting communications with the FDA about whether any JUUL advertisements or proposed advertisements—or other actual or proposed promotional materials—make claims that JUUL helps smokers quit smoking (smoking cessation claims) or claims that JUUL is less hazardous than other tobacco products (modified risk claims).

Response:

The Company is constantly evaluating new ways to reach adult smokers and introduce them to JUUL products as a noncombustible alternative to cigarettes. The Company’s “Enterprise Markets Team” (“EMT”) can play a critical role in these efforts by engaging in business-to-business direct marketing of JUUL products to identified smokers who are over the age of 21.

EMT's objective is to offer business and government entities enterprise solutions such as providing JUUL products through a controlled sales channel, at a discount, to its adult smoker employee-base to transition them from combustible use. Whether employees participate in these offerings is, and will always be, completely voluntary and separate from employment. Moreover, these solutions are not tied to any healthcare plan, and JUUL products are not marketed as "smoking cessation products" to treat nicotine addiction or any other disease or condition associated with nicotine use. Rather, they are a focused sales channel to reach known adult smokers.

JLI has not had any communications with the FDA described in Subpart (d).

- 13. On February 4, 2019, a coalition of 16 conservative-leaning and anti-regulation organizations wrote to President Trump, urging the White House to intervene with the FDA's public health oversight and "pump the brakes on its new regulatory efforts" regarding tobacco products, including e-cigarettes. It has been reported by *The New York Times* that JUUL has made financial contributions to signatories of this letter—including Americans for Tax Reform, the R Street Institute, and the American Legislative Exchange Council Action. Please confirm the amounts and dates of JUUL's contributions to these organizations, as well as the amounts and dates of JUUL's contributions to any other organizations that signed the February 4, 2019, letter.**

Response:

To the best of my knowledge, JLI was not involved in the development or drafting of the referenced letter and was not even aware of it until it was sent to the media. While we have supported some of the groups who signed the letter, our support was not related to the letter.

It is the Company's position that effective regulation of tobacco and vapor products is essential. This includes raising the legal age of purchase for tobacco and vapor products to 21 years of age nationwide. JLI has publicly indicated its openness to work transparently and cooperatively with the FDA, other regulators, and policymakers at all levels of government to advance legislation and regulation that combat underage access to our products and advance the goal of reducing adult smoking in the United States.

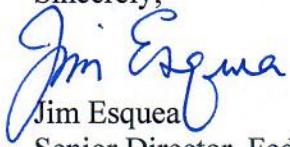
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April 25, 2019

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Thank you for this opportunity to share information regarding the critical issues of reducing adult smoking rates in the United States and combatting youth vaping.

Sincerely,

A handwritten signature in blue ink that reads "Jim Esquea".

Jim Esquea

Senior Director, Federal Affairs
JUUL Labs Inc.